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Statement
of
Thomas Tremble, Associate Vice President, State Government Relations,
the Advanced Medical Technology Association
before the
Connecticut Legislature's Joint Committee on Public Health
On Raised Bill 270

March 1, 2010



Senator Harris, Representative Ritter, and committee members, my name is Thomas Tremble. I am Associate Vice President, State Government Relations with the Advanced Medical Technology Association, or AdvaMed.

AdvaMed is the national association of medical device companies representing more than 1,300 of the world's leading medical technology manufacturers. Over 70% of our member companies are relatively small with sales of less than \$30 million per year. Our members maintain more than a dozen manufacturing facilities in the state.

I want to make clear that AdvaMed strongly supports ethical collaborations among industry and health care professionals (HCPs) and we support appropriate disclosure of relationships between medical technology companies and physicians. We recognize that strong ethical standards are critical to ensuring the valuable collaboration between the medical device industry and health care professionals.

However, we believe that Raised Bill 270 is not the right approach because it threatens beneficial relationships necessary to ensure patient safety and the advancement of medical technology, would be burdensome to comply with and would provide little or no benefit to consumers.

An article in the February 26, 2010 issue of the Boston Business Journal focused on how that state's gift ban is impacting physicians, patients, and jobs. Among the findings of the article:

- A Tufts Medical Center cardiologist said that the gift ban has “put a real chill on Massachusetts doctors’ opportunities to take part in training and clinical research on medical devices.” He went on to say that some educational programs on new procedures have been stopped.
- Fewer clinical trials are being conducted in the state, resulting in less jobs for research staff.
- Companies are no longer involving Massachusetts physicians in pilot programs of new devices to avoid the complication and expense of filing reports.
- Indications are that device manufacturers are more likely to conduct research in other states.

In addition, we understand from our members that the passage of the Massachusetts gift ban law has led to:

- Massachusetts providers being excluded from company-provided educational programs at national conferences because firms generally provide food at these events.



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- Reluctance to locate national seminars in Massachusetts.
- Reluctance to use Massachusetts providers in conducting market research.

Also, compliance for companies has been very technology and labor intensive, which has resulted in significant costs. Expensive new compliance frameworks have had to be established and are difficult to administer. As one example of how much confusion the Massachusetts law has caused for all stakeholders, on February 24th, the Massachusetts Department of Health and Human Services released its fourth guidance document on the regulations. This version even included corrections to a prior guidance. We don't want to have the same kind of problems that have been occurring in Massachusetts happen in Connecticut as well.

In terms of disclosing the relationships, we believe that it is preferable to have a single source of disclosed relationships under a federal framework. A patchwork of state laws with different standards of what types of payments must be disclosed, different details provided, in different formats and for different time periods would be confusing for patients to interpret and place unreasonable burdens on companies. Even with this legislation seeking to mirror the Massachusetts law, it is almost certain that as regulations are developed--which was a lengthy involved process in Massachusetts with multiple guidance documents--variations will emerge.

One comprehensive federal standard for disclosure, such as that in the Grassley-Kohl Physician Payment Sunshine Act, would provide patients with clear information on reportable payments. The federal legislation is included in the health care reform legislation in both the House and the Senate, as well as the President's health care reform proposal.

In addition, we have a strict Code of Ethics which provides clarity between appropriate and inappropriate interactions between health care practitioners and device manufacturers. The latest version of the Code, which took effect on July 1, 2009, prohibits gifts of any type and provides greater guidance relating to company consulting arrangements, and research and educational grants. Further, a listing of companies certifying they are in compliance with the Code is available for public viewing on AdvaMed's web site.

Therefore, because of the problems that have been caused by the Massachusetts law, the obstacles from a patchwork of state oversight in this area, the confusion that would be created for consumers, and the pending federal legislation, we urge the Public Health Committee to not approve this measure.